



#15
**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

July 25, 1986

Robert C. Beck
7000 Central Avenue, N.E.
Minneapolis, MN 55432

Re: Patent Term Restoration Application
U. S. Patent No. 4,467,807

An application for patent term restoration of U. S. Patent No. 4,467,807 issued August 28, 1984 was filed on July 16, 1986. The basis for the application is said to be 35 USC 156. The application was filed on behalf of the owner - Medtronic, Inc.

The subject patent is said to claim a medical device known as the Activitrax Rate Responsive Pacemaker. The application states that the subject medical device was subject to regulatory review that was governed by Section 515 of the Federal Food Drug and Cosmetic Act, and that it received permission for commercial marketing or use on June 10, 1986. The length of the extension of the patent term being requested is 652 days.

The length of the extension which may be granted for a patent eligible for extension is defined in 35 USC 156(c) and is further limited by the provisions of 35 USC 156(g)(4). Only that portion of the regulatory review period which occurs after the date the patent issued is considered in determining the length of the patent term extension. In addition, the period of extension cannot exceed fourteen (14) years from the date of approval of the approved product. 35 USC 156(c)(3). Under the circumstances of this application where the subject patent issued on August 28, 1984, and the product was approved for commercial marketing or use on June 10, 1986, the normal seventeen (17) year term of the subject patent (due to expire August 28, 2001) will not expire until more than one (1) year after the critical limit for an extension of fourteen (14) years from the approval date (i.e. June 10, 2000). Even though the subject patent may meet all requirements of eligibility for patent term restoration under 35 USC 156(a), the application fails to provide a prima facie showing that the term of U. S. Patent No. 4,467,807 could be extended under 35 USC 156.

The application for extension of the term of U. S. Patent No. 4,467,807 is DENIED.

C. E. Van Horn

Charles E. Van Horn, Director
Patent Examining Group 120